REMARKS

In a Restriction Requirement dated January 5, 2005, the claims were subject to a 20 way as follows:

Group I. Claims 1, 13, 14, 59-73 and 97, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:30-32, 62 and 103, class 435, subclass 320.1;

Group II. Claims 2-6 and 38-46, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:46, 119-127 and 131-133, class 435, subclass 320.1;

Group III. Claims 7 and 8, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:51 and 99, class 435, subclass 320.1;

Group IV. Claims 9 and 10, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:55, 57, 96, 101 and 134-135, class 435, subclass 320.1;

Group V. Claim 11, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:58, class 435, subclass 320.1;

Group VI. Claim 12, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:60, class 435, subclass 320.1;

Group VII. Claim 15, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:64 and 66, class 435, subclass 320.1;

Group VIII. Claims 16 and 17, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:68 and 70, class 435, subclass 320.1;

Group IX. Claims 18-21, 33 and 34, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:72, 74, 91, 105, and 107, class 435, subclass 320.1;

Group X. Claims 22 and 23, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:76 and 78, class 435, subclass 320.1;

Group XI. Claims 24-26, and 35, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:80, 81, 83, 93, 94, 109, 111, 113, class 435, subclass 320.1;

Group XII. Claim 27, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:85 and 113, class 435, subclass 320.1;

Group XIII. Claims 28 and 29, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:87 and 115, class 435, subclass 320.1;

Group XIV. Claims 30 and 32, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:89 and 117, class 435, subclass 320.1;

Group XV. Claims 36 and 37, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:96, class 435, subclass 320.1;

Group XVI. Claims 47-51, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:33, class 536, subclass 23.1;

Group XVII. Claims 52-56 and 74-77, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:45, class 536, subclass 23.1;

Group XVIII. Claims 57-58, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO:128, class 536, subclass 23.1;

Group XIX. Claims 78-90 and 92-96, drawn to a method of DNA immunization in a subject, class 424, subclass 93.2; and

Group XX. Claim 91, drawn to a method of generating an immune response in a subject using an HIV polypeptide, class 514, subclass 2;

In addition, the individual sequences of each group were also further restricted (in a restriction, not election of species, requirement) from one another, bringing the number of allegedly independent inventions to at least 58.

A. Traversal of the Restriction Requirement

In a timely filed response (March 7, 2005), Applicants elected, SEQ ID NO:120 of Group II, **with traverse**.

Applicants traversed on the grounds that it would not be unduly burdensome to search all of the sequences classified in elected Group II together and presented evidence regarding the high degree of homology as between the Env-encoding sequences of Group II. Specifically, Applicants noted that, the Examiner's statement that "there are no claims encompassing a generic HIV polypeptide, which indicates that the SEQ ID NOs are independent and there is no disclosure of relationship (percent identity) in the specification between the claimed sequences in each group" was in error. (Restriction Requirement, page 9). Within each group it is clear that each and every sequence encodes a particular HIV polypeptide. Group II, for instance, includes sequences encoding Env polypeptides.

Applicants also cited M.P.E.P. §803.04 with regard to Restriction practice for nucleotide sequences, when nucleotide sequences encode the same protein (*e.g.,* Env as is the case with all sequences of elected Group II):

> [i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined.

Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

Applicants also attached an alignment showing that the homology between the various sequences of Group II is very high.

Accordingly, Applicants requested reconsideration of the Restriction Requirement with respect to Group II noting that all sequences encoding HIV Env proteins may be properly examined together and that it would not constitute an undue burden on the Office to do so (particularly given the high degree of homology between Env-encoding sequences).

B. Requirement Made Final

In an Office Action dated June 2, 2005, the Examiner stated that the arguments traversing the Restriction Requirement were not persuasive. Accordingly, the Restriction Requirement was made FINAL. With regard to M.P.E.P. § 803.04, the Examiner stated that this is "only a guideline and not legally binding" and that this application is not eligible for this option because it is not a SPDI application and that the polynucleotides encode "structurally different envelope glycoproteins."

C. Applicants' Response

In a Response filed August 31, 2005, Applicants again requested consideration of the Restriction requirement, on the grounds that:

- the structure of the polypeptides encoded by the claimed polynucleotides is not relevant to restriction of polynucleotides and/or searching such polynucleotide sequences
- even if the structure of the polypeptides encoded by the claimed polynucleotides were relevant, the Examiner presented no evidence that the claimed polynucleotides encode "structurally different envelope glycoproteins"
- the Examiner also presented no evidence that searching all sequences would be unduly burdensome
- Applicants presented clear evidence regarding the high degree of homology as between the claimed sequences, thereby establishing that searching all sequences together would not be unduly burdensome
- filing at least 58 separate applications would present an serious financial burden on the Applicant and an even more serious search burden on the Office than searching all highly related Env-encoding sequences in one application

D. Petition for Review

For the reasons of record and outlined above, Applicants request reconsideration and withdrawal of the Restriction as between the sequences of Group II, all of which encode HIV envelope glycoproteins.

Indeed, by restricting to a single sequence, the Office has prevented Applicants from claiming the full scope of their invention. M.P.E.P. § 803.02 states, in part:

> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas,* 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

In the case at hand, all Group II sequences share a common utility (encoding an immunogenic HIV Env polypeptide) and possess a substantial structural feature (particular polynucleotide coding sequences) essential to that utility.

The claimed polynucleotides do not differ in structure or function -- they differ only in sequence. Accordingly, the assertion that the sequences are structurally different (along with the irrelevant assertion that they encode structurally different polypeptides) is in error and cannot support the Restriction.

Thus, the claims and sequences of Group II posses unity according to M.P.E.P. § 803.02 and, as such, the Restriction Requirement has prevented Applicants from claiming the full scope of their invention, and is tantamount to a rejection under 35 U.S.C. § 121, which has long been improper. Therefore, Restriction among the different Env-encoding sequences should be withdrawn.

Furthermore, were the Restriction Requirement to be maintained, Applicants would be required to file at least 58 separate applications. At current rates, this is over $70,000 in filing fees alone. Applicants maintain that such expenditures constitute an undue burden, especially as compared to the ease with which the Office can search all Env-encoding sequences together. Furthermore, while Applicants acknowledge that any sequence searching presents a burden to the Office, it is respectfully submitted that examining 58 additional applications would constitute an even more onerous burden on the Office than searching highly related sequences concurrently, particularly in the light of the current (and growing) examination backlog.

Indeed, contrary to the Examiner's assertion that M.P.E.P. § 803.04 only relates to SPDI applications, the Patent Office has clearly recognized that multiple sequences should be searched together, both for the benefit of the applicant and, moreover, relieving the burden on the examiner (*see,* MPEP 2434 at 1192 O.G. 68 (November 19, 1996)):

> The PTO believes that allowing applicants to claim up to ten (10) independent and distinct nucleotide sequences in a single application will promote efficient, cost-effective examination of these types of applications.

For all the reasons of record, and those presented in this Petition, Applicants submit that the Restriction as between individual sequences of Group II is improper and should be withdrawn. Accordingly, Applicants petition for review of the outstanding Restriction Requirement by the Director and for withdrawal of the Restriction Requirement such that all Env-encoding sequences are examined together.

Please direct all further written communications regarding this application to:

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Respectfully submitted,

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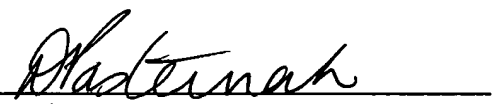
By: 

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